UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

WALGREEN CO. and THE KROGER CO., Plaintiffs, v. BIOGEN, INC., Defendant.	Civil Action No. 1:25-cv-11680 JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co. and The Kroger Co. sue Defendant Biogen, Inc. ("Defendant" or "Biogen") for violations of the federal antitrust laws relating to the market for Tecfidera and its generic equivalents. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This civil antitrust action seeks damages and other relief arising out of Biogen's unlawful scheme to impair competition from generic versions of its brand-name prescription drug Tecfidera, which contains the active pharmaceutical ingredient dimethyl fumarate. Tecfidera is used to treat multiple sclerosis ("MS").

2. The Food and Drug Administration ("FDA") approved Tecfidera in 2013, and it quickly reached blockbuster status, achieving $3.5 billion in U.S. sales by 2015 and remaining in the range of $3.3 to $3.8 billion annually through 2020.

3. These sales reflected Tecfidera's extremely high sales price, which rose to nearly $90,000 per patient per year. Biogen's manufacturing costs were less than $300 per patient per year—*i.e.*, Biogen sold Tecfidera at approximately 300 times its costs. Biogen was able to do so because it owned a patent that, for a time, excluded generic competitors.

4. But that patent was very weak. Beginning in 2017—as soon as legally permissible—numerous generic-drug manufacturers began challenging the validity of the Tecfidera patent. Biogen knew that once it lost those patent lawsuits its Tecfidera sales and profits would fall off the "patent cliff." Generic versions of the drug would quickly take 90% or more of Tecfidera's unit sales and would be sold at a fraction of Tecfidera's price. This competition would save billions of dollars for Plaintiffs and other purchasers of the drug.

5. To forestall this competition and the consequent loss of its sales, Biogen crafted a plan to protect Tecfidera from generic competition. First, it developed a "next generation" version of Tecfidera, called Vumerity. Once ingested, Vumerity and Tecfidera create the same active drug substance—monomethyl fumarate—in the body. They each deliver the same bioequivalent exposure to monomethyl fumarate and therefore have the same effectiveness and safety profile. In fact, Biogen got expedited FDA approval of Vumerity by proving that it was bioequivalent to Tecfidera, *i.e.*, that its active ingredient is present in the patient's blood to the same extent and for the same amount of time. Proving bioequivalence to the branded drug is how generic versions of a drug obtain FDA approval.

6. Vumerity was different from Tecfidera not in a medically important way, but in an *economically* important way. When filling a prescription written for Vumerity, pharmacists could not automatically substitute generic Tecfidera, despite their bioequivalence. So Biogen's plan was to orchestrate a market switch—to get doctors to switch their prescribing from Tecfidera to Vumerity before the generic versions of Tecfidera were available in the marketplace. Biogen would tell doctors and patients that Vumerity was "new and improved" even though in fact it had no medically significant advantages over Tecfidera. If doctors wrote prescriptions for Vumerity rather than Tecfidera, pharmacists could not dispense generic Tecfidera for those prescriptions.

7. As in all pharmaceutical product switches, timing was essential to Biogen's scheme. It is well known in the industry that a switch to a follow-on product like Vumerity—one with no important medical improvements—will succeed only if the switch occurs before generic versions of the original product became available. Once patients have started taking a generic version of the original product, at a lower price, they are very unlikely to switch to the follow-on product and resume paying the higher price.

8. But Biogen ran into problems with respect to the timing of its planned market switch. Biogen's launch of Vumerity was complicated by the onset of the coronavirus disease 2019 ("COVID-19") pandemic, which prevented Biogen's sales force from marketing Vumerity to doctors in-person. And Biogen had planned to get more time to make the market switch by settling the Tecfidera patent lawsuits with an agreement by the generic challengers to delay their entry into the market. That plan went awry because Biogen's patent was so weak that the generic manufacturers refused to settle on those terms. Then when the courts hearing the patent cases ruled that the Tecfidera patent was invalid, the generic manufacturers entered the market immediately, without waiting to see if the invalidity ruling would be upheld on appeal (as it eventually was). This cut 18 months off the time that Biogen thought it would have to make the market switch from Tecfidera to Vumerity.

9. The cumulative effects of Biogen's timing problems were substantial. Instead of reaching its goal of converting nearly 100% of Tecfidera sales to Vumerity before the Tecfidera generics entered the market, Biogen had only converted a small fraction of them.

10. Faced with the prospect of an unsuccessful product switch and the impending loss of Tecfidera sales, Biogen resorted to the unlawful, anticompetitive scheme challenged in this action. Specifically, Biogen entered into unlawful restraints of trade with five of the nation's largest pharmacy benefit managers ("PBMs")—CVS Caremark, OptumRx, Inc.,

Express Scripts, Inc., Humana Pharmacy Solutions, Inc. and MedImpact Healthcare Systems, Inc.—to suppress the normal and expected uptake of generic Tecfidera while it switched the market to Vumerity. Collectively, these five PBMs control pharmacy benefits for more than 90% of Americans. Biogen paid the PBMs to give favored treatment to branded Tecfidera and to disadvantage generic Tecfidera on their formularies—the lists that identify which drugs are covered and establish the applicable patient copayments and/or coinsurance. As a result, patients paid lower or equal copays for branded Tecfidera than for generic Tecfidera and generic Tecfidera was dispensed at a far lower rate than would have occurred in a normal competitive market. That meant that, while the five conspiring PBMs may have benefited from the scheme, wholesalers and retailers were forced to purchase far more units of branded Tecfidera and Vumerity and far fewer units of generic Tecfidera than they would have purchased in a competitive market—*i.e.*, they were overcharged for Tecfidera and Vumerity.

11. The normal practice of PBMs is to place generic versions of branded drugs on a more favorable tier on their formularies than branded drugs, thereby encouraging the use of the generics and serving the interests of their clients. In this case, Biogen paid each of the five conspiring PBMs to disadvantage generic Tecfidera over branded Tecfidera and Vumerity on their formularies, contrary to their normal practice. Biogen labeled these payments as "rebates" or "fees." They were in fact kickbacks to the PBMs for helping to insulate Tecfidera and Vumerity from lower-priced generic competition.

12. While the PBMs passed some of the rebates (none of the fees) on to some of their clients, the rebates were not legitimate and honest ways for Biogen to compete with generic Tecfidera on price. For example, in 2022 generic Tecfidera was selling at a 93% discount off the list price of branded Tecfidera. In contrast, Biogen's average rebates and fees on branded Tecfidera were less than 28% off the list price. Biogen's rebates and fees were payments *to the*

PBMs in exchange for excluding the generics, not price reductions that, even if fully passed on to them, would have produced savings anywhere near what the generics offered. And even if the rebates and fees could be characterized as price reductions, they were not price reductions to wholesalers and retailers, which paid more for the drug and got nothing in return.

13. These manipulations substantially suppressed the substitution rate of generic Tecfidera and impaired the competitive effect of generic entry. That period of impaired competition, in turn, gave Biogen the time it needed to switch a large portion of the market from Tecfidera to Vumerity. Whether the product switch was independently unlawful or not, it would not have occurred at all, or it would have been far less successful, but for Biogen's anti-competitive scheme.

14. Biogen also paid the PBMs to impose on generic Tecfidera the same dispensing restrictions that they imposed on Tecfidera. Most PBMs had previously designated Tecfidera as a "specialty drug." The agreements between Biogen and the five conspiring PBMs required them to designate generic Tecfidera as a specialty drug also. But nothing about generic Tecfidera required special handling or treatment—it is a shelf-stable pharmaceutical dispensed as a pill. Designating generic Tecfidera as a specialty drug was a means of steering distribution of the drug in favor of the specialty pharmacies affiliated with the five conspiring PBMs.

15. Biogen's requirement that the PBMs impose the same dispensing restrictions on generic Tecfidera also caused the generic versions to be subject to step edits and prior authorizations—red tape designed to inhibit patients from buying the generic.

16. To minimize the chance that any portion of the market could work unimpaired, Biogen also provided "coupons" that insureds could use to eliminate their copayment or coinsurance when they filled their prescription with branded Tecfidera. Like the formulary-placement tactic, this anticompetitive tool also obscured the price signals that the

insureds received. The coupons made it appear to the insureds that generic Tecfidera cost more than brand Tecfidera. Again, Biogen's anticompetitive tactic gave insureds false price signals about the products' relative *total* costs.

17. These four Biogen tactics—payments to distort formulary placement, payments conditioned on specialty-drug designations, payments to impose step edits and prior authorizations, and providing copayment and coinsurance coupons—worked individually and holistically to impair competition from generic Tecfidera. Collectively, these Biogen tactics affected the purchases of well over 75% of all insureds in the country.

18. Biogen's conduct had the intended effect. With unimpaired generic competition, generic Tecfidera would have rapidly replaced branded Tecfidera in the pharmaceutical distribution chain. Under normal circumstances, within ten months of generic availability, pharmacies would have been dispensing about 2.2 million units of generic Tecfidera every month. Instead, they were dispensing about a third of that amount. The difference between the expected substitution of generic Tecfidera and its actual substitution represents units of the drug that Plaintiffs were required to purchase in the form of branded Tecfidera or Vumerity at monopoly prices rather than in the form of generic Tecfidera at competitive prices.

19. Plaintiffs seek damages, permanent injunctive relief and all other appropriate relief for Biogen's wrongdoing.

II. PARTIES

20. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Tecfidera and Vumerity, to the public. Walgreen brings this action in its own behalf and as the assignee of AmerisourceBergen Drug Corporation, a pharmaceutical wholesaler, which during

the relevant period purchased Tecfidera and Vumerity directly from Biogen for resale to Walgreen and which has expressly assigned its claims arising out of those purchases to Walgreen.

21. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Tecfidera and Vumerity, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal Health, Inc., a pharmaceutical wholesaler, which during the relevant period purchased Tecfidera and Vumerity directly from Biogen for resale to Kroger and which has expressly assigned its claims arising out of those purchases to Kroger.

22. Defendant Biogen Inc. ("Biogen") is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 225 Binney Street, Cambridge, Massachusetts. Biogen is a manufacturer and seller of branded prescription pharmaceuticals, including Tecfidera and Vumerity. It regularly conducts business throughout the United States, including in this judicial district.

23. Although not named as Defendants, CVS Caremark, OptumRx, Inc., Express Scripts, Inc., Humana Pharmacy Solutions, Inc., MedImpact Healthcare Systems, Inc. and their affiliates conspired with Biogen in violation of the antitrust laws and assisted Biogen in carrying out its unlawful scheme.

III. JURISDICTION AND VENUE

24. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and seeks damages and injunctive relief pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26.

25. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

26. Venue is proper in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b)-(c) because, during the relevant time period, Biogen resided, transacted business, was found, or had agents in this district and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district.

27. This Court has personal jurisdiction over Biogen because it, either directly or through the ownership and/or control of their subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this district; and (b) was engaged in an illegal scheme that was directed at, and had a direct, substantial, reasonably foreseeable, and intended effect of, causing injury to the business or property of persons and entities residing, located, or doing business in the United States, including in this district.

III. REGULATORY AND ECONOMIC BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

28. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

29. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit

pharmacists from dispensing many pharmaceutical products, including Tecfidera, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) is obligated to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

30. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

31. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power or monopoly power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

32. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a

New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

33. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within thirty days of their issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

34. The FDA relies completely on the brand manufacturer's representations about patent validity and applicability, as it does not have the resources or authority to verify the validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

35. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. It must only show that the generic drug contains the same active ingredient(s), dosage

form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug. In other words, the ANDA must demonstrate that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

36. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

37. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic manufacturers, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

38. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had increased many-fold to $300 billion.

D. Paragraph IV Certifications

39. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

40. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement Action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

41. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from generic versions of the drug marketed by other ANDA filers. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This 180-day exclusivity period is extremely valuable to generic companies. When only one generic is on the market, the generic price, while lower than the branded price, is much higher than it is after

multiple generic sellers enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generics on the market. Being able to sell at the higher price for six months may be worth hundreds of millions of dollars.

E. Benefits of Generic Drugs

42. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as those operated by Plaintiffs, a generic drug typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies like Biogen view competition from generic drugs as a grave threat to their bottom lines.

43. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists dispense the generic version whenever possible when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for brand prescriptions unless one of the following conditions applies: (a) the prescribing physician has specifically countermanded that substitution by writing "dispense as written" or equivalent language on the prescription; (b) the patient asks the pharmacist to

dispense the brand (and is willing to pay for it); or (c) dispensing the generic would be equally costly or more costly to the patient than dispensing the brand.

44. In the vast majority of cases there is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also typically benefit from the lower prices of generic products. PBMs are supposed to represent the interests of their clients (health insurers and benefit plans) and typically encourage the use of AB-rated generics by giving them favorable formulary treatment, which results in lower copays for generics as compared to their brand-name equivalents. However, as this case demonstrates, PBMs can also be persuaded to abandon their clients and serve the interests of branded pharmaceutical companies like Biogen. All it takes is money.

45. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market.

46. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly or the absence of AB-rated generic competition. Patents are routinely invalidated or held unenforceable, either upon reexamination or in *inter partes* proceedings by the U.S. Patent and Trademark Office (PTO), by court decision, or by jury verdict. A patent holder always bears the burden of proving infringement.

47. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

48. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated and/or obvious in light of earlier prior art; (ii) its claims are indefinite, lack sufficient written description, or fail to properly enable the claimed invention; (iii) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; and/or (iv) when the invention claimed in a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception or safe harbor applies).

49. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

50. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

51. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its ANDA does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

F. Role of PBMs and Specialty Pharmacies

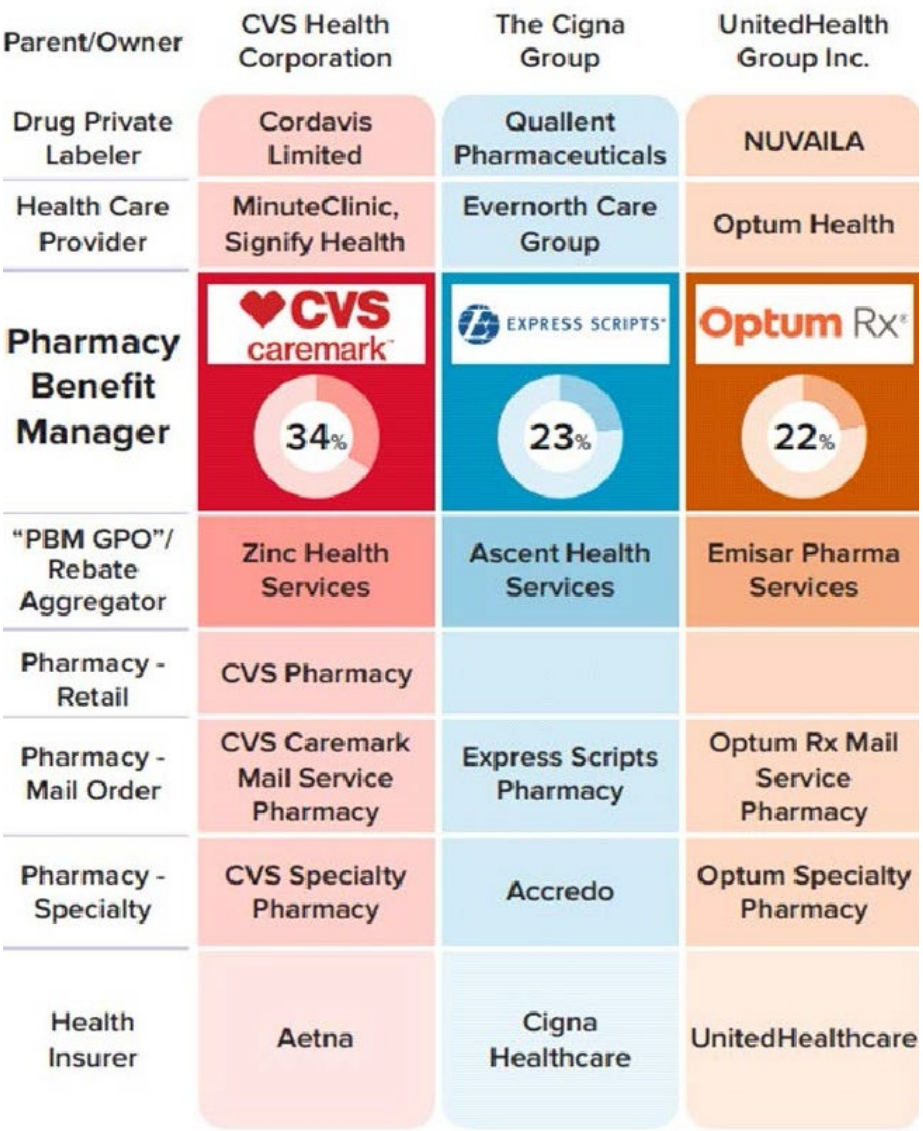
52. PBMs are third-party entities that manage prescription drug benefits on behalf of their clients, which include health insurance companies, self-funded health plans, large employers, and governmental entities. PBMs create pharmacy networks. Those networks include mail order and specialty pharmacies in addition to the more familiar chain and independent pharmacies. Many mail-order pharmacies and some specialty pharmacies are either owned by a PBM or share common ownership with a PBM.

53. Over the past 20 years, the PBM marketplace has become increasingly concentrated. In 2004, the top three PBMs served a combined 190 million people and managed 52% of prescription drug claims. Today, the three largest PBMs manage about 80% of prescription drug claims, for about 270 million people. The five Co-conspirator PBMs collectively control over 90% of all prescription drug claims.

54. Each of the five Co-conspirator PBMs has become vertically integrated with various entities along the pharmaceutical supply chain, insulating them from competition by creating barriers to entry for any non-integrated entity that wants to provide competing PBM services. This gives them even greater power and control over the distribution and pricing of drugs than their dominance in PBM services alone already provides. Each PBM's vertical integration gives it near complete control of the pricing, dispensing, and reimbursement system for all prescription drugs for its covered lives. This control permits the PBM to work with drug manufacturers to drive up drug prices and foreclose patients' access to competitors' less costly

drugs. The result is increased profits for the PBMs and brand manufacturers, and higher drug prices for consumers and health plans.

55. This graphic depicts each PBM's vertical integration with midstream distributors, including retail, mail order, and specialty pharmacies. Each is also vertically integrated with a health insurer that controls drug coverage for hundreds of millions of Americans.



56. Especially relevant here are the "specialty pharmacies" that the PBMs sometimes include in their pharmacy networks. A specialty pharmacy primarily dispenses "specialty drugs" and may be a brick-and-mortar pharmacy or a mail order pharmacy. The vast majority are mail order pharmacies. Historically, specialty drugs were characterized by their need for special handling and administration.

57. Today, however, PBMs exercise unregulated discretion in classifying drugs as specialty medications. Some PBMs designate a drug as specialty based solely on its high cost. When a PBM vertically integrates with a specialty pharmacy, it has an increased ability to steer patients to its own in-house specialty pharmacy and toward more expensive drugs—in exchange for payments from brand manufacturers.

58. Specialty drugs account for a growing share of pharmacy dispensing revenue (about 40-50%) but only a small fraction of total prescription volume (about 2%). A PBM's designating a product as a specialty drug may trigger provisions in its contract with a health plan that require the insureds to fill the prescription only at the PBM's affiliated specialty pharmacy. The five Co-conspirator PBMs' specialty pharmacies account for approximately 70% of all specialty-drug revenue.

59. In 2023, CVS Specialty, an affiliate of CVS Caremark, earned $73.3 billion in revenues from specialty drugs, which accounted for 30% of all prescription revenues from specialty drugs. Accredo, owned by Express Scripts, earned $59.5 billion in revenues from specialty drugs, which accounted for 24% of all prescription revenues from specialty drugs. And Optum Specialty Pharmacy, owned by UnitedHealth Group, earned $32.3 billion in revenues from specialty drugs, which accounted for 13% of all prescription revenues from specialty drugs. CenterWell Specialty Pharmacy, owned or controlled by Humana, earned $6.2 billion in revenues from specialty drugs, which accounted for 3% of all prescription revenues from

specialty drugs. Overall, mail order pharmacies accounted for more than three-quarters of the industry's $243 billion in total prescription revenues from specialty drugs.

60. Other economic trends in the PBM marketplace confirm that the consolidation and vertical integration in the PBM industry has warped PBMs' incentives, diminished competition among them, and set the stage for brand-drug manufacturers to cause economic harm to drug purchasers.

61. For example, the PBMs have begun accepting rebates and "fees" from brand manufacturers in exchange for skewing their formularies to favor higher-priced brand drugs over low-cost generic drugs. The brand manufacturers and PBMs win; patients and health plans lose. Similarly, by prioritizing specialty and branded drugs over generics, PBMs can raise drug prices and push consumers toward more expensive options, decreasing the use and availability of lower-cost generics.

62. The PBMs and brand manufacturers, including Biogen, have created a "hide-the-ball" system where the consideration that the manufacturer pays to the PBMs (and does not share with payors) is labeled and relabeled. As more health plans required PBMs to pass a majority of the manufacturer "rebates" through to them, PBMs started renaming the payments in order to keep a larger portion of them. Payments once known as "rebates" are now called administrative fees, volume discounts, service fees, data usage fees, inflation fees, or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged.

63. The PBMs perform no services for these unearned fees or payments. In return for these fees paid by brand manufacturers, including Biogen, the only thing the PBMs do is disadvantage and suppress lower cost drugs.

64. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the brand manufacturers tripled, reaching more than $16 billion. That growth in "fees" has continued to accelerate since 2016.

65. In short, health plans cannot defeat the PBMs' accepting payments from brand manufacturers. Health plans may choose which pharmacy networks and drug formularies to use among the PBM's offerings based on health plan designs, but information asymmetries hinder their ability to make fully informed decisions. So most health plans accept the standard formularies that the PBMs offer or otherwise defer to their formulary recommendations. Indeed, health plans hire PBMs for their expertise, including in formulary management.

66. From 2016 to 2024, the total revenues of the CVS healthcare conglomerate rose from $177.5 billion to $372.8 billion. Those of the Cigna healthcare conglomerate rose from $39.7 billion to $247.1 billion. Those of the United Healthcare conglomerate rose from $184.8 billion to $400.3 billion, and those of the Humana healthcare conglomerate rose from $54.4 billion to $117.8 billion. They also expanded their operating profits; these four conglomerates' combined profits rose from $14.1 billion in 2016 to more than $24.6 billion in 2024.

67. PBMs began as a partial solution to the problem of brand-drug manufacturers' market power. Formularies and other competitive tools were capable of generating some competition among branded drugs, and of promoting generic drugs after brand-drug patents expired. But once these commercial behemoths achieved dominance up and down the pharmacy distribution chain, they have proved only too willing to wield that dominance as a mechanism of exclusion at the behest of brand-drug manufacturers. In exchange for payments

from the brand-drug manufacturers, the PBMs have thwarted the generic competition that is their legitimate role to promote.

G. Anticompetitive Tactics by Drug Manufacturers

68. Over the years, brand manufacturers have developed an arsenal of anticompetitive tactics to impair generic competition. Two are most relevant here.

69. One tactic to impair generic competition is to prevent automatic generic substitution. Generic manufacturers do not employ sales forces of "detailers" who call on doctors and try to persuade them to prescribe one drug rather than another. Generic manufacturers rely on automatic substitution at the pharmacy counter. That is the most cost-effective means for them to generate sales and profits.

70. Brand manufacturers can seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product for the purpose of preventing the anticipated generic product from being AB rated to the new brand product. Once the new version is approved, the brand manufacturer can use its sales force to switch the market from the old product to the new one, ensuring that when generic versions of the old product enter the market there is no market for them.

71. The timing of the switch is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. If the timing is tight, a planned market switch may create a need to delay generic competition or (as in this case) to suppress the uptake of the generic while the market switch is carried out.

72. Brand manufacturers know that, if they successfully cannibalize the original product's sales before the generics enter the market, the generics are not likely to *ever* compete effectively for those switched prescriptions. Automatic substitution at the pharmacy counter is a generic product's only commercially viable means of competing. As noted above, the price disconnect is the problem and AB-rated automatic substitution by pharmacies is the solution designed by Congress and state legislatures.

73. The second anticompetitive tactic relevant here is enlisting PBMs in the service of impairing generic competition. The vertical integration and market concentration have made it profitable for the PBMs to accept kickbacks from the brand manufacturers to impair generic competition.

74. The brand manufacturer and the PBMs have a collective economic interest in impairing generic competition. If they work together to hinder generic competition, they can keep the profit margins on all the unit sales high and split the resulting excess profits among themselves. They can keep the enormous savings that generic competition would have delivered to drug purchasers.

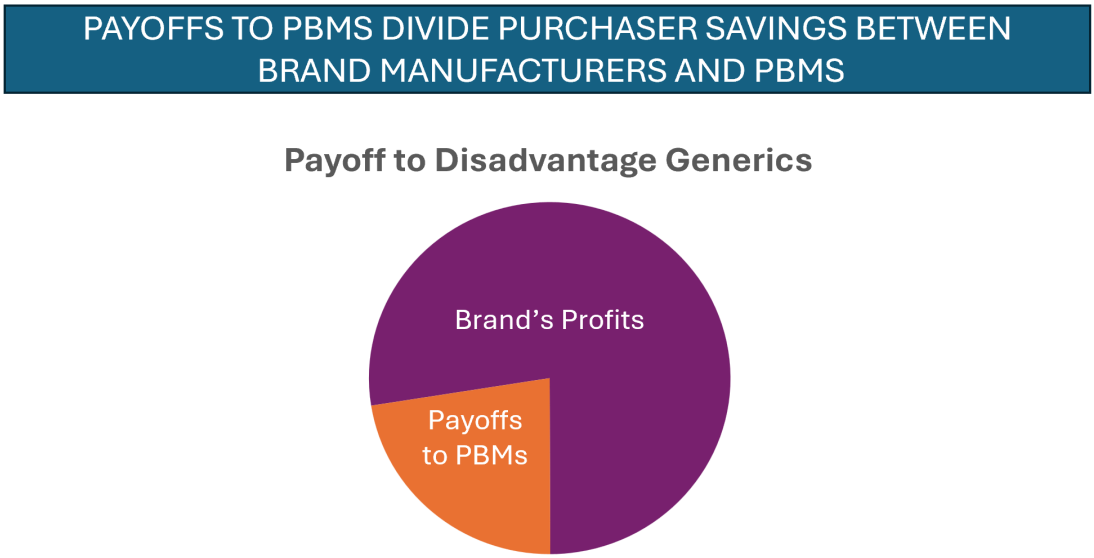
75. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales:

BRAND HAS ALL PROFITS

76. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings:

GENERIC COMPETITION DELIVERS SAVINGS TO PURCHASERS

77. To avoid this result, the brand manufacturer can pay the PBM to impair generic competition. The reduced competition keeps the brand manufacturer's profits high, and the manufacturer can use a portion of those extra profits to make the payment to the PBM. The brand manufacturer and the PBM win; purchasers lose:



78. In order for this anticompetitive pact to work, the brand manufacturer needs a means by which to divide the extra profits with the PBM. The PBM will not help impair generic competition if it does not share in the ill-gotten gains. Kickbacks from the brand manufacturer are the way it divides the ill-gotten gains with the PBM.

79. Biogen paid kickbacks—denominated as rebates and/or fees—to each of the five Co-conspirator PBMs. In exchange, the PBMs agreed to disadvantage lower cost generic Tecfidera over branded Tecfidera and Vumerity. The motivation for the scheme was Biogen's plan to switch the market from Tecfidera to Vumerity. Product switches or "hops" like the one planned by Biogen have been held unlawful in some cases, but whether or not the market switch from Tecfidera to Vumerity was unlawful standing alone, it would not have occurred at all or

would have been far less successful absent the unlawful scheme to suppress competition from generic Tecfidera. Thus, absent the unlawful scheme to suppress competition from generic Tecfidera, all or nearly all of Plaintiffs' purchases of Vumerity would have been purchases of generic Tecfidera at much lower prices.

IV. OPERATIVE FACTS

A. Multiple Sclerosis is a Chronic Disease for Nearly One Million Americans.

80. MS is a chronic autoimmune disease that affects the central nervous system. The disease is characterized by the immune system's attacking the protective sheath (myelin) that covers nerve fibers, leading to communication problems between the brain and the rest of the body. Almost one million people in the United States have been diagnosed with MS.

81. Although the symptoms and signs of MS can vary, the interruption of signals to the brain generally causes numbness, blindness, mood changes, memory problems, pain, fatigue, and/or paralysis. Other symptoms include lack of coordination, unsteady gait or inability to walk, prolonged double vision, blurry vision, vertigo, slurred speech, and cognitive problems.

82. MS most commonly presents in the relapsing remitting form. Patients will go through cycles of disease flair ups, experiencing symptoms that typically improve fully or partially over time. Remission of the disease tends to follow flair ups, but the length of remission varies.

83. The cost of living with MS is very high. Direct medical costs such as doctor's appointments and the cost of drugs are some of the biggest contributors to the high cost of living with MS. There is no cure for MS.

B. Biogen Made Billions Selling Tecfidera at Extremely High Prices.

84. Biogen is a global biopharmaceutical company that manufactures, promotes, and distributes prescription drugs. On March 19, 2013, the U.S. Patent and Trademark office issued a patent for Tecfidera (dimethyl fumarate). In the same year, the FDA approved Tecfidera for the treatment of MS, and it quickly became one of Biogen's top-selling drugs. Biogen touted Tecfidera's effectiveness in reducing MS relapses, delaying the progression of physical disability associated with MS, and slowing the development of MS-related brain lesions.

85. By 2015, Biogen's U.S. sales for Tecfidera were $2.9 billion, which was nearly half of Biogen's total U.S. product sales ($6.5 billion) for that year. Tecfidera's significant contribution to Biogen's U.S. sales continued throughout the rest of the decade:

Year	Tecfidera US Sales	Total Biogen US Product Sales
2016	$3.1 billion	$7.0 billion
2017	$3.2 billion	$7.0 billion
2018	$3.2 billion	$6.8 billion
2019	$3.3 billion	$6.7 billion

86. Biogen consistently raised Tecfidera's price to increase its total revenue and profits. For example, according to Biogen's 2016 Annual Report, "the increase in U.S. Tecfidera revenues was primarily due to price increases, partially offset by higher discounts and allowances and a decrease in unit sales volume of 1%." Biogen's Annual Reports likewise cited price increases as the reason for increased Tecfidera sales revenue from 2016 to 2017 and from 2018 to 2019.

87. Consequently, as of 2019 the average retail price of Tecfidera was $124.67 per pill (approximately $90,000 for an annual supply at two pills per day), up from an original 2013 price of about $71.87 per pill (approximately $52,500 for an annual supply at two

pills per day)—a 73.5% increase. During that same period, the Consumer Price Index increased by only 9.7%.

88. From 2013 until generic Tecfidera became available in 2020, branded Tecfidera was essentially a must-have for any formulary. In light of its importance to sufferers of MS, PBMs had little choice but to include Tecfidera on their formularies. Excluding Tecfidera would have meant denying access to a primary therapy for MS patients.

C. Biogen Planned to Defeat Generic Competition to Tecfidera.

89. Beginning in 2017, Biogen found itself on the defensive as it confronted a series of challenges to its patent on Tecfidera. These patent challenges threatened Tecfidera's patent protections, which Biogen had relied on to secure its market exclusivity and significant profit streams. Biogen knew that, if the patent challenges succeeded, early entry of generic competition would significantly reduce its profitability from this key product.

90. So Biogen developed a strategy to maintain the monopoly profits from its Tecfidera franchise even if its patent were invalidated. The plan was to move as many Tecfidera prescriptions as possible to a follow-on product before generic Tecfidera became available.

91. The follow-on product was Vumerity (diroximel fumarate). The development of Vumerity began with a U.S. patent application submitted in September 2013 by Alkermes plc ("Alkermes"), a Dublin-based pharmaceutical firm. That patent was issued on March 31, 2014 and expires on October 29, 2033.

92. Alkermes developed the formulation of diroximel fumarate in partnership with Biogen. Despite this early start in development, Biogen did not file a New Drug Application for diroximel fumarate until December 2018. The FDA granted approval for the drug in October 2019.

93. Biogen obtained FDA approval for Vumerity by using the studies that showed that *Tecfidera* was safe and effective and that Vumerity is bioequivalent to Tecfidera. Showing bioequivalence to Tecfidera is also how manufacturers of generic Tecfidera obtained FDA approval for their drugs.

94. The active ingredient in Vumerity is diroximel fumarate, while the active ingredient in Tecfidera is dimethyl fumarate. Although diroximel fumarate and dimethyl fumarate have different chemical structures and pharmacokinetic properties, the human body converts both of them to the same molecule—monomethyl fumarate. And it is monomethyl fumarate that provides both drugs' therapeutic effects.

95. Biogen began selling Vumerity in 2019, marketing it on the asserted ground that it leads to fewer side effects—gastrointestinal problems—than Tecfidera.

96. An analysis of the clinical trial that serves as the basis for Biogen's claims suggests that the actual improvement in gastric intolerance with Vumerity is likely minimal, if it exists at all. Vumerity's purported average improvement was *one fewer day* of gastric upset. For MS patients who take these drugs over an extended time (as is typical) and for existing users of Tecfidera, there is no material difference.

97. Notably, the FDA-approved label for Vumerity does not include any claims of superiority of Vumerity over Tecfidera with respect to side effects or otherwise.

98. Instead, there is reason to believe that Vumerity is *inferior* to Tecfidera. Switching from Tecfidera to Vumerity doubles the patient's pill burden—the number of pills the patient must take every day. And a patient's pill burden significantly affects the likelihood that she will adhere to the prescribed therapy. The fewer pills she must take, the more likely she is to adhere to the drug regimen, to avoid drug resistance, to have a better quality of life, and to have a better health outcome.

99. More than 25% of people with MS take five or more prescription medications. They often treat multiple symptoms with multiple medications which can lead to high medication or pill burden. Increasing the number of pills taken to treat the same symptoms does little to improve the treatment regimen for these patients. Failure to adhere to the therapy is associated with the development of drug resistance, toxicity, and lack of potency, among many other complications, including death.

100. Biogen's own conduct confirms that conclusion. When it began selling Vumerity in October 2019, and continuing from that time to the present, Biogen sold Vumerity for *less than* Tecfidera. For example, in 2019 Biogen's list price for a day's supply of Tecfidera was $249, versus $228 for a day's supply of Vumerity. In 2021 the list prices were $258 for Tecfidera versus $235 for Vumerity.

101. Biogen's promotional efforts in markets outside the United States further confirm that Vumerity is not a medical improvement over Tecfidera. In those non-U.S. markets, where Tecfidera still has patent protection, Biogen has continued to focus on promoting Tecfidera over Vumerity. In 2022, Biogen's Tecfidera sales outside the U.S. were more than $1 billion, many times higher than its Vumerity sales of just $32 million.

D. Biogen Planned, but Failed, to Switch the Market to Vumerity Before Generic Tecfidera Entered the Market.

102. As noted above, it was essential to Biogen's market-switch strategy that it move the prescription base from Tecfidera to Vumerity before generic Tecfidera became available.

1. Biogen Readied Vumerity If It Lost the Patent Litigation.

103. Biogen's patent protection was under attack on multiple fronts when Biogen filed for FDA approval of Vumerity in December 2018. Biogen sued several generic-drug manufacturers for patent infringement because they had filed ANDAs seeking FDA

approval of their generic Tecfidera products. The generic manufacturers responded by alleging that Biogen's patent was invalid.

104. One of the federal cases, between Biogen and Mylan Pharmaceuticals ("Mylan"), was pending in the Northern District of West Virginia. Biogen's other patent cases against generic manufacturers proceeded on a parallel track in the District of Delaware. Both cases were set for trial—one scheduled for December 2019 and the other for February 2020—when Biogen filed its NDA for Vumerity in December 2018.

105. In addition to the federal litigation, in February 2019, Mylan instituted an inter partes review ("IPR") challenge in the U.S. Patent and Trademark Office. Mylan's IPR proceeding also sought to invalidate the last remaining patent that protected Tecfidera, U.S. Patent No. 8,399, 514 (the "514 Patent").

106. Amid the uncertain climate of ongoing patent litigations for Tecfidera, Biogen told its investors that, if the Tecfidera patent were invalidated, it could switch the market to Vumerity. As Biogen told investors during an investor call: "Importantly, ahead of the outcome of the IPR and District Court and the Litigations, we shall have the opportunity to launch VUMERITY, a novel oral fumarate disease-modifying treatment that has the potential to be another important choice for MS patients." Biogen explained that "[i]t is a priority that we appropriately maximize the potential of VUMERITY."

107. During that same investor call, an analyst asked, "Am I hearing it correct and also should we reasonably expect a meaningful switch ahead of IPR decision?" Biogen's CEO responded, "So from day one and this is the reason why we did the – we deployed capital and acquired this asset [the license from Alkermes] is that it was meaningful and strategically important for the company." He elaborated that "[i]t would be premature to state on any clear tactical plan or strategy for launch. But while we speak, we are working thoroughly on that."

108. A month later, the Biogen CEO again told investors that "obviously, the patent situation will certainly have an entrance into the tactical plan of launching VUMERITY. But for that, we are working hard and time will tell, okay? The important situation, again, is that VUMERITY will be launched months or quarters before the court ruling on the [Tecfidera] IP."

109. Biogen later advised its investors that, "if we're unsuccessful with either the two district court cases, we've got VUMERITY as a product that we can kind of look at, is a fumarate strategy that we're looking at."

2. Biogen's Sole Motive Was to Impair Generic Tecfidera.

110. Biogen's sole motive in developing and marketing Vumerity was to use it in the strategy to defeat competition from generic Tecfidera. Biogen's decision to incur the extra costs (and suffer the revenue losses) associated with switching the market from Tecfidera to Vumerity was economically rational only because the switch had the exclusionary effect of impairing generic competition and maintaining Biogen's monopoly. But for the impact on generic competition, Biogen would not have invested the resources necessary to reformulate and cannibalize Tecfidera because doing so would have been a money-losing proposition.

3. Biogen Was Unable to Time the Market Switch.

111. Biogen knew that if it switched the prescription base to Vumerity before generic Tecfidera entered the market, doctors would not later switch them back to generic Tecfidera. This general proposition is particularly true with respect to MS. Patients stay on a particular MS medication for long periods of time. Those patients like to stay on a drug once they find one that works. They do not want to risk unnecessary symptoms or complications by switching drugs.

112. The trouble for Biogen started with the outbreak of the COVID-19 pandemic in March 2020. Biogen's market-switch strategy relied on in-person sales pitches to

prescribing doctors. Given the minimal to non-existent clinical differences between Tecfidera and Vumerity, Biogen needed to rely on personal contacts with the doctors to convince them to switch.

113. Those in-person contacts became very difficult once COVID-19 hit. Biogen later reported to its investors that "it's important to note that the MS market in the US has been significantly impacted by lower new patient starts and switches due to COVID-19, as well as reduced engagement with physicians, which have both impacted the launch of VUMERITY."

114. Another problem arose when Biogen was unable to settle the patent lawsuits with the generic manufacturers. In July 2019, Biogen told its investors that "there was a lot of interest" in settling the patent litigations. Biogen anticipated that it could settle the patent litigations with agreements by the generic manufacturers to delay entering the market until years later. Biogen would use that delay to switch the market from Tecfidera to Vumerity.

115. Biogen's confidence that it could delay generic entry through settlements was misplaced. Despite its best efforts, Biogen was unable to reach settlements with Mylan and other generic manufacturers before those cases went to trial. The bench trial in the Delaware case went forward in December 2019, and the bench trial in the West Virginia case proceeded in February 2020.

116. On June 18, 2020, the U.S. District Court for the Northern District of West Virginia found that Biogen's '514 patent was invalid. The district court in Delaware reached the same conclusion on September 16, 2020.

117. After the first decision, in July 2020, Biogen advised investors that "[g]oing forward, our strategic focus is now on VUMERITY, and we are increasing our resource allocation to maximize this next-generation fumarate." The CEO emphasized that "now the

entire focus is pivoting on VUMERITY….” Biogen was making “a significantly enhanced focus of the organization on one brand, VUMERITY.”

118. Biogen’s Executive Vice President & Chief Medical Officer had told investors in 2019 that “physicians that I talked to would not want to switch somebody who’s done well who’s stabilized [after] the initial phases of taking TECFIDERA and are doing well in terms of tolerability.” But Biogen abruptly changed its position once competition from generic Tecfidera was imminent.

119. Biogen started using its army of sales force detailers to cannibalize the Tecfidera prescriptions, *i.e.*, to aggressively switch those prescriptions to Vumerity. Among many other marketing tactics, Biogen implemented “incentive schemes” for its salesforce, conditioning top pay to converting as many Tecfidera prescriptions as possible to Vumerity.

120. Beginning in late 2020, patient attempts to visit the Tecfidera webpage were automatically intercepted by a different webpage informing them of another option – Vumerity. From that page, patients could either choose to visit the Vumerity webpage or continue to the Tecfidera site.

121. Even after losing both of the patent cases in the district courts, Biogen thought it still had time to switch the market to Vumerity before the entry of generic Tecfidera.

When the brand drug has sales of the magnitude that Tecfidera achieved—more than $3 billion annually—generic manufacturers will sometimes wait to enter the market despite a win in the district court. If they enter the market and the patent victory is later overturned on appeal, they may be liable to the brand manufacturer for patent infringement. On a drug like Tecfidera, those damages can be substantial, and generic manufacturers are not always willing to take that kind of risk.

122. Accordingly, Biogen told its investors in July 2020—after Biogen's first loss to a generic manufacturer at trial—that Biogen "assumed no generic entry for Tecfidera" in 2020. But Biogen's planning was wrong again. Its patent was so weak that the generic manufacturers did not wait for an appellate decision before entering the market.

123. On August 17, 2020, the FDA approved Mylan's ANDA for dimethyl fumarate. Mylan announced the launch of its generic Tecfidera capsules on August 19, 2020. Several additional generic competitors entered the market over the ensuing months. As a result, Biogen's plan to switch the market to Vumerity before the generics entered the market was overtaken by events.

E. Biogen Paid the Major PBMs to Impair Generic Competition.

124. Biogen's poor timing prevented it from switching the market to Vumerity prior to the launch of generic Tecfidera. Biogen therefore moved to plan B—impeding the substitution of generic Tecfidera by enlisting the help of the PBMs. This conspiracy to impede generic substitution violated the antitrust laws.

125. Even though generic Tecfidera was *available* for sale, Biogen paid the three major PBMs to ensure that it was *not in fact dispensed to patients*. Biogen then used this period of impaired generic competition to switch as many prescriptions as possible from Tecfidera to Vumerity.

126. With the impending entry of generic Tecfidera, the PBMs finally had the opportunity to generate huge savings for the health plans and the insureds. As noted, generics usually take 90% of the brand sales within a year of generic entry. And the generics sell at massive discounts off the brand price.

1. Biogen paid increased rebates and fees to PBMs for Impairing Generic Tecfidera

127. PBMs almost always heavily promote the low-price generic substitute because doing so lowers costs for their clients. For example, CVS Health's Form 10-K for 2023 states that the company "helps its PBM clients control costs by recommending plan designs that encourage the use of generic equivalents of brand name drugs when such equivalents are available." Here, in less than a year after entering the market the generics were selling for about $17 per pill while brand Tecfidera was about $132 per pill.

128. As noted above, the PBMs' principal way to promote generics is to place them on the lowest (the best) tier on the formulary—usually Tier 1. Correspondingly, the PBMs place the counterpart brand drug on the highest (the worst) tier—usually Tier 5.

129. Biogen paid each the major PBMs not to follow their normal practice and instead to disadvantage generic Tecfidera as compared to brand Tecfidera or Vumerity. It paid increased rebates and fees to PBMs if they agreed not to place the generics on a better tier than branded Tecfidera and Vumerity, as they normally would. As a result, the vast majority of patients paid lower or equal co-pays for branded Tecfidera and branded Vumerity as compared to generic Tecfidera, requiring retailers to dispense the branded drugs rather than the generic.

130. The PBMs are not in the pharmaceutical distribution chain. They are not themselves drug purchasers. The PBMs are agents that negotiate formulary placement and prices on behalf of the health plans and the insureds. In paying rebates and fees to the PBMs, Biogen was not competing with generic Tecfidera on price. It was paying agents—the PBMs—to harm

their principals by impairing that competition and thereby giving Biogen time to conduct the market switch.

131. Drug wholesalers and retailers (like Plaintiffs' assignors and Plaintiffs, respectively) received no portion of these rebates and fees. Moreover, the rebates and fees, even if fully passed on to the PBMs' clients, would not have produced savings anywhere near what the generics offered.

132. If Biogen had been engaged in genuine price competition, the list price of Tecfidera minus all rebates/fees would have been close to the price of generic Tecfidera and would have declined as the price of generic Tecfidera declined. That is not at all what happened.

133. Instead, the list price of Tecfidera minus all rebates/fees fell from $115 per pill in 2019, to $112 in 2020, to the *low point of $75 in 2021*, and then *rose* substantially to $100 in 2022, and $110 in 2023. In contrast, the retail prices of generic Tecfidera were dramatically lower, and they substantially *and steadily* decreased over time. They did not, as Biogen's net prices did, increase after the critical year 2021. They continued to substantially decline.

134. And the conspiring PBMs knew that Biogen was using the time that it bought from them to switch the market from Tecfidera to Vumerity. The PBMs did not initially favor Vumerity over Tecfidera on their formularies. If Vumerity had exhibited medically significant advantages over Tecfidera, in terms of clinical effectiveness or patient tolerability, the PBMs would have placed Vumerity in a superior position on their formularies as soon as Vumerity was available. They did not.

135. The PBMs participated in the anticompetitive scheme and actively facilitated it because Biogen handsomely paid them to do so.

2. Biogen paid PBMs to designate generic Tecfidera as a specialty drug.

136. Nothing about generic Tecfidera required special handling—it is a shelf-stable pharmaceutical dispensed in pill format. Biogen nevertheless paid the Co-conspirator PBMs to designate generic Tecfidera as a specialty drug.

137. The purpose and effect of requiring that designation was to make patients incur a very high copayment or coinsurance for generic Tecfidera, significantly reducing their incentive to accept the generic. Another purpose and effect was to require that the falsely designated product be dispensed only through a small number of specialty pharmacies, shielding those pharmacies—owned by the PBMs—from price competition from other pharmacies. Biogen knew and intended that this would substantially depress the sales of generic Tecfidera by keeping its price to health plans and other purchasers astronomically high.

138. The concentration and vertical integration in the PBM industry ensured that competition among the PBMs would not dissuade any one of them from designating generic Tecfidera as a specialty drug. All five Co-conspirator PBMs are affiliated with a specialty pharmacy; all five shared a desire—absent effective competition among them—that its specialty pharmacy make these outlandish profits on the sale of generic Tecfidera; and each of the five knew that Biogen was offering the same kickbacks to the other four.

3. Biogen paid the PBMs to impose step edits and prior authorization requirements on generic Tecfidera.

139. Biogen paid enhanced rebates and fees to the Co-conspirator PBMs in exchange for their using "utilization management" techniques against generic Tecfidera. The purpose and effect of those techniques was to substantially impair the sale of generic Tecfidera. The payments subjected more than 68% of insureds to formularies that placed generic Tecfidera on a tier other than Tier 1 and/or that imposed a step edit or prior authorization on generic Tecfidera.

140. Two of the utilization-management techniques that Biogen paid the PBMs to use against generic Tecfidera were "step edits" and "prior authorizations." With a step edit the PBM requires the insured to fill a prescription for some other drug before it will cover the drug that is the subject of the step edit.

141. For example, a PBM might legitimately require the insured to first try—use as a first "step"—a more effective drug, or an equally effective but less expensive one, before getting the targeted drug.

142. But Biogen's payment for a step edit against generic Tecfidera was wholly illegitimate and anticompetitive. Even when generic Tecfidera was nominally on the first (best) tier of the formulary, Biogen paid enhanced rebates and fees to PBMs to use a step edit that required insureds to first try another MS drug—including sometimes requiring that they first try Tecfidera or Vumerity—before becoming eligible for coverage of generic Tecfidera.

143. Biogen also paid the PBMs to require "prior authorization" before the insured could purchase generic Tecfidera. This requirement mandated that the patient's doctor make a formal request to the PBM to approve coverage of generic Tecfidera. Again, in other circumstances prior authorization requirements might play a legitimate role. Their only role here was to delay and impair the uptake of the dramatically less expensive generic Tecfidera.

144. PBMs originally developed these utilization-management techniques in order to engender price competition among similarly high-priced branded alternatives within a therapeutic class. Here, Biogen wielded these techniques *against* price competition—paying PBMs to promote the high-price brands over the much-lower-priced generics.

4. Biogen's agreements with the major PBMs suppressed generic competition.

145. Biogen's conduct had its intended effect of significantly impairing competition from generic Tecfidera.

146. The five Co-conspirator PBMs collectively control more than 90% of pharmacy benefit services in the United States. As a result of their agreements with Biogen, virtually every one of the formularies maintained by those PBMs disadvantaged generic Tecfidera vis-à-vis branded Tecfidera and branded Vumerity, resulting in millions of patients continuing to take branded Tecfidera (and eventually branded Vumerity) rather than generic Tecfidera. Plaintiffs (and their assignors) were forced to buy the branded drugs at monopoly prices in order to fill those prescriptions.

147. Like the other Biogen anticompetitive restraints, these anti-generic tactics were widespread. For example, Biogen paid the Co-conspirator PBMs to place generic Tecfidera on a tier other than Tier 1 and/or to impose step edits or prior authorization requirements on generic Tecfidera on formularies covering about 68% of insureds.

148. Of particular note is that, absent the payments from Biogen, no legitimate rationale can explain why a PBM would forgo placing generic Tecfidera—a drug available at massive discounts off the price of the brand—on the lowest tier, with no roadblocks like step edits or prior authorizations. Yet Biogen's payments overturned that competitive outcome.

149. In addition to impairing or eliminating price signals, Biogen's copayment-parity tactic altogether disabled automatic generic substitution for a substantial portion of the relevant sales. Many state generic-substitution laws prohibit the pharmacist from automatically substituting the generic product for the corresponding brand product unless the patient will pay *less*—not merely the same—for the generic.

150. The chart attached as Appendix A identifies the states whose laws prohibit automatic substitution unless the patient pays less for the generic. About 48.8% of the U.S. population lives in those states. Biogen's payments to the PBMs prevented generic substitution in those states.

151. Of the remaining states, 14—Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin—require generic substitution, but only if the patient will pay less for the generic. *See* Fla. Stat. § 465.025(2); Haw. Rev. Stat. § 328-92 (a); K.R.S. 217.822(1), (3); Mass. Gen. Laws ch. 112, § 12D; M.S.A. § 151.21(3), (4); Nev. Rev. Stat. § 639.2583(1), (3); N.J. Stat. § 24:6E-7; N.Y. Educ. Law § 6810 6(a), (c); N.Y. Educ. Law § 6816-a; 35 Pa. Stat. § 960.3(a); R.I. Gen. Laws § 5-19.1-19; R.I. Gen. Laws § 5-37-18.1; R.I. Gen. Laws § 21-31-16.1; Tenn. Code § 53-10-204(a); Tenn. Code § 53-10-205(a); VT ST. T. 18 § 4605; W. Va. Code § 30-5-12b; Wis. Stat. Ann. § 450.13. About 30.8% of the U.S. population lives in these states. Biogen's payments to the PBMs disabled mandated substitution in these states.

152. Altogether, about 79.8% of the U.S. population lives in states where Biogen's payments to the Co-conspirators not only affected price signals to the insureds, but directly prohibited automatic substitution or disabled mandated automatic substitution.

153. This chart lists the PBM, the year, and the percent of insureds on the PBM's formularies that placed generic Tecfidera on a tier other than Tier 1 and/or imposed the paid-for step edits or prior authorizations on generic Tecfidera:

PBM	2021	2022	2023	2024
CVS Caremark	68%	69%	66%	62%
Express Scripts	54%	60%	44%	46%
OptumRx	87%	86%	82%	82%
Humana	98%	96%	93%	95%
MedImpact	50%	50%	44%	41%
All Five PBMs	68%	71%	64%	61%

154. In the years 2021 to 2024 generic Tecfidera should not have been placed above Tier 1, or with restrictions, on formularies covering *any* insureds. Instead, Biogen paid for a *substantial majority* of insureds to be subjected to one or both of those disadvantages. From

2021 to 2024 the percentage of insureds who were subjected to those restraints were 68%, 71%, 64%, and 61%, respectively.

155. In total, well more than 75% of insureds were affected by one or more of the improper tier placement, specialty-pharmacy designation, or utilization-management aspects of Biogen's scheme.

156. The other 25% (or less) may have been only indirectly affected by Biogen's offers to pay the PBMs. But that is not the result of health plans' decisions specifically regarding generic Tecfidera. Instead, the PBMs, not the health plans, made the decisions as to whether, and to what extent, to accept Biogen's payments in exchange for disadvantaging generic Tecfidera.

157. The PBMs made those decisions based on their own financial goals. PBMs have detailed information regarding the current and expected drug usage for each particular health plan that it manages. So PBMs can and do accept or decline rebate and fee offers from brand drug manufacturers to maximize the PBMs' profits on a plan-by-plan basis.

158. A variety of considerations (e.g., the number of plan members who take the drug, rebate offers from other brand manufacturers, and the margin that the PBM's specialty pharmacy made on the drug) affected the PBMs' analyses as to whether and to what extent to accept Biogen's payments with respect to particular plans. The PBMs, not the health plans, made those decisions. The fact that the PBMs made different decisions with respect to different health plans does not imply otherwise.

5. Biogen used patient coupons to undermine price signals and impair generic uptake.

159. Biogen also delayed and impaired competition from generic Tecfidera by undermining the incentives that some formularies put in place to encourage insureds to buy the generics. Thus, even when Biogen had not succeeded in paying to rig a formulary against generic

Tecfidera, Biogen still anticompetitively undermined insureds' incentives to choose the dramatically lower-cost generics.

160. Biogen undermined those incentives by offering to pay the copayments or coinsurance of Tecfidera patients, thus falsely making generic Tecfidera appear to be more expensive than Tecfidera. Biogen made the copayment/coinsurance "coupons" available to all Tecfidera patients, and some 33% likely used them.

161. Requiring that insureds pay a copayment or coinsurance helps to align the insureds' economic interests and incentives with those of the health plans. Insureds, not the health plans, decide which prescription drugs to purchase, but the health plans pay the vast majority of the cost. Copayment and coinsurance requirements make insureds more sensitive to price and overcome the price disconnect described above.

162. Simply put, an insured is more likely to buy a generic drug for which she pays a $20 copayment than the brand-drug version with a $50 copayment. The same is true for an insured who must pay 20% coinsurance for a $75 generic rather than a $300 brand drug. These cost-share obligations provide essential price signals for insureds to properly weigh relative costs, allowing market forces to determine which products are bought, and at what price.

163. Biogen undermined these price signals and economic incentives for insureds in private health plans (not Medicare or Medicaid), even when it had not otherwise already rigged the formularies against generic Tecfidera. Instead of competing with generic Tecfidera on price, Biogen devised a scheme to bypass the price signals that would have prompted insureds to select generic Tecfidera.

164. Biogen gave "coupon" cards to insureds that eliminated the copayments and coinsurance that otherwise would have guided them to appropriately consider price when choosing between Tecfidera and generic Tecfidera. Generic manufacturers generally cannot

Case 1:25-cv-11760 Document #: 1-7 11 Filed: 09/26/25 Page 43 of 60 PageID #:43

provide patient coupons. Generic drugs are commodities, and a manufacturer that issued a coupon for using a generic version of a drug could not ensure that the coupon would be used to buy its version rather than a competitor's. And generic manufacturers' generally thin margins could not support such a program in any event.

165. Except (presumably) in states that prohibit such coupons (California and Massachusetts), Biogen made the coupons available to *all* insureds with private health-plan coverage who had been prescribed Tecfidera. Insureds' eligibility for the coupons did not depend on their ability to pay or other need-based criteria. Biogen ensured that the coupons would eliminate price signals that *all* of these private-plan insureds otherwise would have received as to the relative costs of generic Tecfidera versus branded Tecfidera.

166. Under the Biogen scheme, pharmacies accepted the Biogen coupons from the insureds in lieu of collecting the otherwise required copayment or coinsurance. Biogen then reimbursed the pharmacy for the value of the coupon. The insureds could receive Tecfidera, having paid little or nothing out of their own pockets. Generic manufacturers cannot economically provide such coupons, so Biogen's scheme arranged for insureds who used the coupons to actually pay *less* for Tecfidera than they would have paid for the less expensive generic Tecfidera.

167. These anticompetitive effects are so substantial and obvious that the federal government has outlawed the use of such coupons with respect to federal drug-benefit plans.

168. A prominent Stanford health-policy researcher, whose specialties include empirical research on drug prices, concluded that these coupon programs "effectively counteract health plans' efforts to encourage patients to choose less expensive alternatives by placing them in formulary tiers with lower cost sharing . . . These programs have driven a wedge between the

perceived interests of patients and those of their health plans. They are highly effective in inducing prescriptions for branded drugs: in one study, they increased branded-drug sales by sixty percent, with commensurate reductions in sales of generic drugs." Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?,* 102 Minn. L. Rev. 2273, 2291 (2018).

169. Congressional investigators with access to some brand manufacturers' internal documents similarly confirmed that these patient coupon programs are anticompetitive, especially when used in the face of generic competition. The investigators "obtained internal discussions and strategy documents in which companies … emphasized the rates of return of their copayment assistance programs for commercial patients. Internal [company] documents emphasized that its copayment program encouraged patients to stay on branded [drug] even after the entry of generic competition." *Drug Pricing Investigation*, Committee on Oversight and Reform, U.S. House of Representatives, Majority Staff Report (Dec. 2021).

170. The brand manufacturers use the coupons as "public relations tools," but their internal documents "emphasized the significant returns on investment from these programs in the form of increased sales, particularly for drugs approaching loss of exclusivity." *Id*. at xiv. "Internal documents indicate that enhanced copay programs were a crucial piece of [the brand manufacturer's] loss-of-exclusivity strategy for [the brand drug], encouraging patients to stay on the branded drug even after generic entry." *Id*. at 157. The manufacturers' documents showed a huge return on investment—from 450% to nearly 900%—in the coupon programs, as they substantially muted generic uptake. *Id*. at 154, 157.

E. Biogen's Scheme Foreclosed Generic Competition.

171. Biogen's comprehensive anticompetitive scheme had exactly the anticompetitive effects that make the conduct unlawful.

172. With free and open competition, generic Tecfidera would have rapidly eroded the Tecfidera sales base. Congress, all 50 states, and the FDA have cleared the pathways for generics to enter quickly, and in force, as soon as patent barriers have been cleared away. The statutory and regulatory policy "is designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharmaceutical Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

173. Absent Biogen's conduct, generic Tecfidera would have brought to the market the benefits that Congress intended. As of August 2020, when the courts found Biogen's patent invalid, Tecfidera had annual sales of about $3 billion. Sales of that magnitude typically attract entry by numerous generic manufacturers, and that occurred here. By October 2020, seven generic manufacturers had entered the market and begun selling generic Tecfidera.

174. The price of generic drugs to wholesalers and retailers is determined by the price of the branded drug and the number of generic sellers. With seven generic manufacturers in the market, wholesale generic prices are typically competed down to a 90% discount off the brand drug within six to nine months of entry. And that happened here. By February 2021, the manufacturers were selling generic Tecfidera to wholesalers and retailers at discounts of 89% off the price of brand Tecfidera.

175. Generic manufacturers also rapidly take unit sales away from the brand product. With just a few manufacturers in the market, and often with only one, the generics typically take more than 90% of the pre-generic-entry unit sales within the first 10 months.

176. Biogen's unlawful conduct prevented that from happening with respect to generic Tecfidera. The generics were *available* from more than a half dozen manufacturers and were sold at competitive prices. But Biogen's conduct targeted a different point in the distribution chain: despite the competitive wholesale prices, Biogen's scheme interfered with and prevented the generics *actually being dispensed* to insureds.

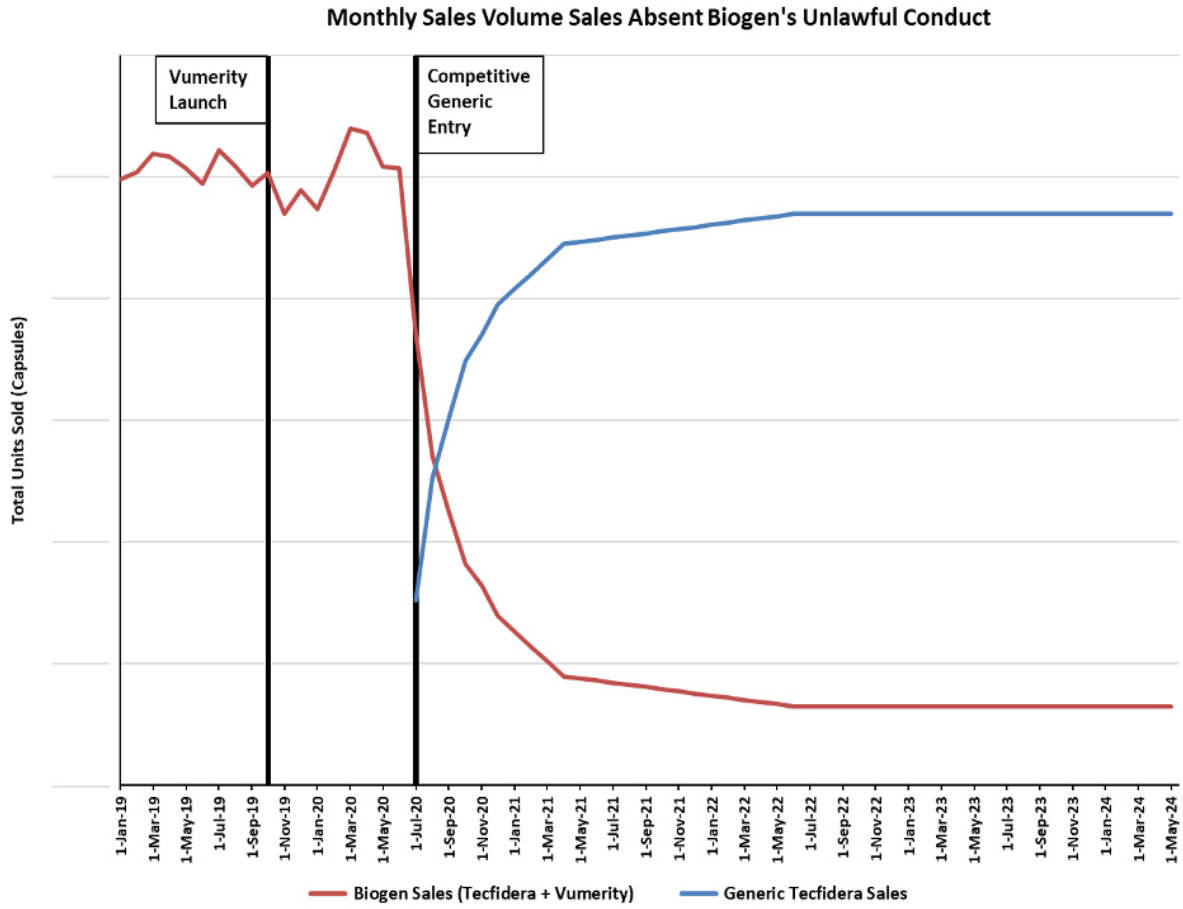
177. As a result of Biogen's conduct, by June 2021—ten months after generic entry—generic Tecfidera had garnered less than a third of the unit sales. This compares to the typical generic penetration rate of 90+%. By June 2022, generic Tecfidera had garnered only 47%; as late as June 2024—nearly four years after generic entry—the generic sales were only 55%. As a result, Plaintiffs and their assignors were required to purchase millions of units of branded Tecfidera and branded Vumerity at monopoly prices that would otherwise have been units of generic Tecfidera at competitive prices.

178. Given the dramatically lower prices at which generic Tecfidera was available, Biogen's scheme impairing generic uptake caused massive harm to the market. Biogen's impairment of competition from generic Tecfidera during the period August 2020 to April 2024 cost purchasers more than $3 billion in lost savings.

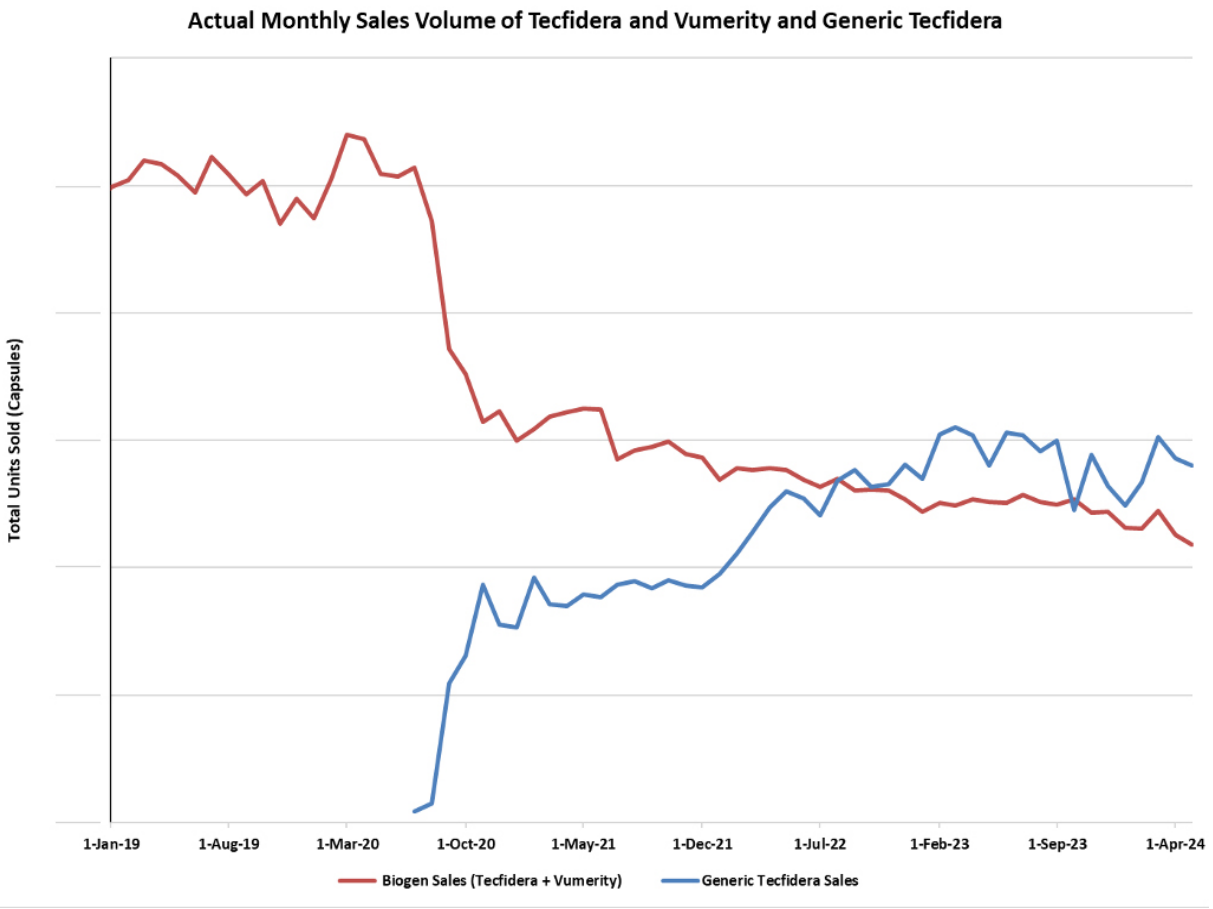
179. Biogen's scheme also belatedly allowed it to switch the market from Tecfidera to Vumerity. In May 2020, before the courts invalidated Biogen's patent and it started switching the market in earnest, Vumerity had monthly unit sales of only 50,225 capsules (equal to only 419 thirty-day supplies at four capsules per day). That was just 1% of thirty-day supplies compared to Tecfidera's sales of 2,495,616 capsules (equal to 41,594 thirty-day supplies at two capsules per day). By June 2021 Vumerity's monthly unit sales had sky-rocketed to more than 733,897 capsules (equal to 6,116 thirty-day supplies at four capsules per day). At that time, Biogen's Vumerity sales accounted for more than 29% of its combined sales of Tecfidera and Vumerity. Almost all of those sales came from prescriptions that, absent Biogen's market switch, would have been for Tecfidera and filled with the generic.

180. Had Biogen not implemented that scheme, by June 2021, 90% or more of the relevant prescriptions would have been filled with generic Tecfidera.

181. Absent Biogen's unlawful conduct, its combined unit sales of branded Tecfidera and Vumerity, compared to sales of generic Tecfidera, would have looked approximately like this:



182. As a result of Biogen's payoffs to the PBMs and other anticompetitive conduct, its actual combined unit sales of branded Tecfidera and Vumerity during that same timeframe, compared to sales of generic Tecfidera, looked approximately like this:



183. Biogen's unlawful conduct substantially foreclosed generic competition by denying generic manufacturers a fair opportunity to compete using state generic-substitution laws. Biogen's campaign to interfere with the competitive process resulted in purchasers buying brand Tecfidera and Vumerity despite the availability of more affordable generic Tecfidera.

184. Only brand manufacturers—not generic manufacturers—pay rebates and fees to PBMs. So the PBMs shared Biogen's incentive to have as many prescriptions as possible switched from Tecfidera to Vumerity, not to the generic. The PBMs will go on collecting rebates and fees on Vumerity into the future—the patents on Vumerity do not expire until 2033.

185. Manufacturers do not pay any rebates or fees to PBMs on generic Tecfidera. The economic benefits of generic Tecfidera flow to actual drug purchasers, not to the PBMs.

186. Those losses will continue to accrue absent effective injunctive relief from this Court. As of May 2024, Vumerity has a sales base of more than a million units per month. No generic is available for that product. Absent Biogen's unlawful conduct, Vumerity would have a prescription base of less than 200,000 units per month.

F. Biogen Directly Reduced the Supply of Generic Tecfidera.

187. Biogen also directly intervened in the sales of generic Tecfidera, preventing generic sales that would have occurred in a competitive market.

188. An authorized generic ("AG") is a prescription drug made by a brand-drug manufacturer but marketed under a generic label. AGs typically compete, like other generics, at much lower prices than the brand product. With sales of the magnitude of Tecfidera, a competitive market—one unimpaired by the brand manufacturer's anticompetitive conduct—almost always features the brand manufacturer's sale, either directly by itself or through a third party, of an AG.

189. Teva is a pharmaceutical company that markets both brand and generic drugs. On the brand side, Teva is a leader in MS medications, marketing branded and generic MS treatments.

190. Teva was among the many generics that sought to market a generic of Tecfidera. Teva sought to market its own generic Tecfidera product under ANDA No. 210290.

191. On or about August 25, 2020, however, Biogen and Teva entered into an agreement for Teva to market an AG of Tecfidera rather than launching its own generic Tecfidera under its own ANDA. Under this agreement, Biogen agreed to sell Tecfidera to Teva,

which Teva would then market as the AG of Tecfidera. Teva would pay Biogen a royalty on sales of the Teva AG. Biogen provided a launch notice to Teva designating September 15, 2020 as the launch date for the authorized generic of Tecfidera.

192. Teva launched in September 2020 and, by the end of 2020, Biogen and Teva's AG had captured a significant share of generic Tecfidera sales. Despite this success, Biogen decided to eliminate the AG Tecfidera because of the threat that it posed to Vumerity. In March 2021, Biogen suspended the AG agreement with Teva and then, in April 2021, terminated it.

193. On May 5, 2023, Teva brought a breach of contract and unjust enrichment action against Biogen. Teva alleged that Biogen terminated the agreement because generic Tecfidera was taking sales from Vumerity: "It appears that, upon realizing the full scope of competition from other generic versions of Tecfidera®, and in light of the possibility that Product sold by Teva might take sales from other medicines in its portfolio also approved for treatment of MS [i.e., Vumerity], Biogen decided to cut bait on the Product…."

194. The threat that generic Tecfidera posed to Vumerity was so acute that Biogen even refused to permit Teva to sell the shipments of Tecfidera that Biogen had already transferred to Teva. That product expired and had to be destroyed.

195. This is yet another instance of Biogen incurring significant costs not in order to compete, but to impair the competition that otherwise would have occurred.

G. Biogen's Scheme Had Substantial Anticompetitive Effects.

196. Biogen's scheme to suppress generic competition to Tecfidera has substantially and artificially suppressed the sale of generic Tecfidera and has allowed Biogen to charge purchasers monopoly prices for dimethyl fumarate and diroximel fumarate. By delaying

the onset of full generic competition, Biogen deprived would-be generic manufacturers of the most efficient means of distribution under the governing statutes and regulations.

197. Biogen's anticompetitive conduct, and the PBMs' participation in it, unlawfully prevented purchasers of Tecfidera and Vumerity from obtaining the benefits of unimpaired generic competition.

198. Biogen's scheme and unlawful payments harmed Plaintiffs (and their assignors) by causing them to purchase significantly more units of branded Tecfidera and Vumerity and significantly fewer units of generic Tecfidera as compared to the quantities they would have purchased in a competitive market. The difference between what Plaintiffs' assignors paid to acquire those drugs and what they would have paid to acquire them in a competitive market constitutes overcharges.

V. MARKET POWER AND RELEVANT MARKET

199. At all relevant times, Biogen had substantial market power in the market for Tecfidera and its AB-rated generic equivalents. Biogen had the power to maintain Tecfidera prices at supracompetitive levels without losing sufficient sales to other products to make the supracompetitive prices unprofitable.

200. Biogen had the ability to control the prices of fumarate and exclude relevant competitors. Direct evidence of Biogen's market power includes the following: (a) from 2013 through the present Biogen's per-unit manufacturing cost for fumarate has been less than 15% of the net price of the drug, *i.e.,* the price after adjusting for rebates and discounts; (b) Biogen never lowered the price of fumarate to the competitive level in response to pricing of other brand or generic drugs; and (c) from launch in April 2013 to June 2020, Biogen profitably raised the price of Tecfidera by approximately 79%. During that period, the Consumer Price Index rose by only 10.7%.

201. To the extent that Plaintiffs are required to prove market power by defining a relevant product market, Plaintiffs allege that, for the purpose of evaluating the competitive effect of Biogen's conduct, the relevant product market is the market for Tecfidera, Vumerity, and their AB-rated generic equivalents (collectively, "fumarate") and narrower markets therein. At all relevant times, Biogen had market power in the fumarate market because it had the power to raise or maintain the price of fumarate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

202. A small but significant, non-transitory increase in the competitive price of fumarate did not cause a significant loss of sales. At competitive prices, Biogen's fumarate does not exhibit significant, positive, cross-elasticity of demand with respect to price with any MS drug other than AB-rated generic Tecfidera.

203. Biogen needed to control only fumarate, and no other products, in order to maintain the price of fumarate products profitably at supracompetitive prices. Only the unimpaired market entry of a competing, AB-rated generic version of Tecfidera would render Biogen unable to profitably maintain supracompetitive prices for those products.

204. Doctors generally select MS drugs for their patients based on the clinical and pharmacological attributes of the drug and the patients' relevant characteristics, rather than principally on price. For clinical reasons, among others, physicians and patients prefer fumarate to other MS drugs for certain patients. Due to, among other reasons, its use and effectiveness in reducing MS relapses, delaying the progression of physical disability associated with MS, and slowing the development of MS-related brain lesions fumarate is significantly differentiated from all products other than AB-rated generic Tecfidera.

205. Fumarate's medical and clinical attributes significantly differentiate it from other MS drugs. Other MS drugs have different chemical compounds and formulations, and the FDA does not consider them to be interchangeable with fumarate.

206. Biogen advised its investors in April 2020 that the entry of another MS drug pill, Banner's Bafiertam, would not "significant[ly] impact" Tecfidera's sales. Bafiertam is monomethyl fumarate, which produces the same active metabolite as Tecfidera. Biogen explained that despite the chemical similarities, Bafiertam would not significantly affect Tecfidera's sales because Bafiertam "is not a directly substitutable A/B product."

207. Biogen's statement proved to be accurate. As of May 2024, Bafiertam sells only approximately 46,000 capsules per month (383 thirty-day supplies at 4 capsules per day). Less than 2% of the combined dimethyl, monomethyl, and diroximel fumarate unit sales are of Bafiertam.

208. At all relevant times, Biogen enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of drug development, entry, and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

209. Until July 2020, Biogen's market share in the relevant market was 100%. From July 2020 through the present its dollar share of the market has exceeded 85%, and its unit share has been as high as 95% and has always exceeded 45%. Biogen's anticompetitive conduct has shielded approximately 800,000 monthly unit sales of fumarate from generic competition.

210. The relevant geographic market is the United States.

VI. INTERSTATE COMMERCE

211. The drugs at issue in this case were manufactured and sold in interstate commerce, and the unlawful conduct alleged herein occurred in, and had a substantial effect on, interstate commerce.

VII. ANTITRUST IMPACT

212. During the relevant time period, Plaintiffs' assignors purchased substantial quantities of Tecfidera and Vumerity directly from Biogen. Biogen's unlawful scheme has forced Plaintiffs and their assignors to purchase more units of branded Tecfidera and Vumerity at monopoly prices, and fewer units of generic Tecfidera at competitive prices, than they would have paid in a competitive market, resulting in overcharges. The exact amount of overcharges will be calculated after discovery and subject to proof at trial.

213. Plaintiffs' assignors are direct purchasers from Biogen, the sole defendant and principal antitrust violator. The overcharges paid by Plaintiffs' assignors as a result of Biogen's anticompetitive scheme—*i.e.*, the difference between what they paid for the relevant drugs in the actual world and what they would have paid absent the unlawful scheme and conspiracy—were paid directly to Biogen. Those overcharges were not passed on to Plaintiffs' assignors by any intermediary because there is no such intermediary. As a result of their assignments, Plaintiffs are now the owners and prosecutors of their assignors' direct-purchaser claims.

214. Because of the somewhat unusual nature of this case, there are *two* sets of direct purchasers in this litigation. First, as just noted, the wholesalers that purchased Tecfidera and Vumerity directly from Biogen, including Plaintiffs' assignors, are direct purchasers. In most pharmaceutical antitrust cases, wholesalers that purchased the relevant drug directly from

the defendant drug manufacturer are the only direct purchasers in the case. Retailers (not holding assignments), third party payors and patients are all indirect purchasers.

215. In this case, however, there is a second set of direct purchasers. Employee health plans and other payors that purchased Tecfidera and Vumerity at retail directly from specialty pharmacies owned by the three conspiring PBMs are also direct purchasers because they purchased directly from a co-conspirator of Biogen (or an entity owned and controlled by a co-conspirator of Biogen). As in the case of direct-purchasing wholesalers, the overcharges paid by those health plans to those specialty pharmacies were not passed on to them by an intermediary because there is no such intermediary.

216. Plaintiffs and their assignors have sustained and will continue to sustain substantial loss and damage to their business and property in the form of overcharges.

217. Biogen's unlawful conduct threatens continuing loss and damage to Plaintiffs unless enjoined by this Court.

VIII. CLAIMS FOR RELIEF

CLAIM ONE: MONOPOLIZATION (15 U.S.C. § 2)

218. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 217 above.

219. Biogen unlawfully monopolized the market for Tecfidera and its generic equivalents in the United States.

220. At all relevant times, Biogen possessed substantial market power (i.e., monopoly power) with respect to Tecfidera and its AB-rated generic equivalents. Biogen possessed the power to control prices in the relevant market and to exclude competitors from the relevant market.

221. As alleged above, Biogen willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than by competing on the merits. That conduct included (a) paying the PBMs to distort formulary placement, (b) payments to the PBMs conditioned on specialty-drug designations, (c) payments to the PBMs to impose step edits and prior authorizations, and (d) providing copayment and coinsurance coupons. Those elements of the scheme worked individually and collectively to impair and suppress competition from generic Tecfidera.

222. Biogen's conscious objective was to further its dominance through exclusionary conduct.

223. Biogen's anticompetitive conduct was undertaken with the purpose and effect of maintaining Biogen's monopoly power in the relevant market, to the detriment of Plaintiffs and other purchasers of the drug.

224. There is no cognizable, non-pretextual, procompetitive justification for Biogen's exclusionary conduct that outweighs its harmful effects. Even if there were some justification that Biogen were permitted to assert, its conduct was broader than necessary to achieve such a purpose.

225. As a result of Biogen's anticompetitive scheme, Plaintiffs' assignors were forced to purchase units of branded Tecfidera and Vumerity at monopoly prices that would otherwise have been units of generic Tecfidera purchased at competitive prices.

226. Plaintiffs and their assignors have been injured and will continue to be injured in their business and property as a result of Biogen's unlawful monopolization. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Biogen's conduct unlawful.

CLAIM TWO: CONSPIRACY IN RESTRAINT OF TRADE
(15 U.S.C. § 1)

227. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 217 above.

228. In or about September 2020, Biogen entered into agreements with five of the largest PBMs in the United States under which Biogen agreed to pay the PBMs fees and rebates and, in return, the PBMs agreed to disfavor generic Tecfidera and to favor branded Tecfidera and Vumerity in the ways specified above. In a competitive market, generic Tecfidera would quickly have taken approximately 90% of Tecfidera's sales at lower, competitive prices. Instead, the generic substitution rate was artificially suppressed and the prescriptions that continued to be filled with branded Tecfidera were available to be switched to branded Vumerity, a drug without generic competition.

229. The agreements between Biogen and the five Co-conspirator PBMs had a substantially adverse effect on competition in the relevant market. They allowed Biogen to continue to extract monopoly profits from their customers despite the availability of less expensive generic Tecfidera.

230. The collusion between Biogen and the major PBMs was undertaken with the purpose and effect of maintaining Biogen's monopoly power in the relevant market and sharing the profits resulting from that monopoly with the PBMs, to the detriment of Plaintiffs and other purchasers of the drug.

231. There is no cognizable, non-pretextual, procompetitive justification for Biogen's exclusionary conduct that outweighs its harmful effects. Even if there were some justification that Biogen were permitted to assert, its conduct was broader than necessary to achieve such a purpose.

232. As a result of Biogen's anticompetitive scheme, Plaintiffs' assignors were forced to purchase units of branded Tecfidera and Vumerity at monopoly prices that would otherwise have been units of generic Tecfidera purchased at competitive prices.

233. Plaintiffs and their assignors have been injured and will continue to be injured in their business and property as a result of the unlawful conspiracies in restraint of trade. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Biogen's (and its co-conspirators') conduct unlawful.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Biogen and for the following relief:

A. A declaration that the conduct alleged above is in violation of section 2 of the Sherman Act;

B. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled as provided by law;

C. Permanent injunctive relief enjoining and restraining Biogen from continuing its unlawful conduct and requiring it to take affirmative steps to dissipate the continuing effects of that prior unlawful conduct;

D. An award of Plaintiffs' costs and reasonable attorneys' fees, as provided by law; and

E. Such other and further relief as the Court may deem just and proper.

X. JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: September 26, 2025

Respectfully submitted,

/s/ Trevor K. Scheetz

Trevor K. Scheetz
SPERLING KENNY NACHWALTER LLC
321 N. Clark Street, 25th Floor
Chicago, IL 60654
Telephone: (312) 641-3200
Email: tsheetz@sperlingkenny.com

Scott E. Perwin (*pro hac vice* forthcoming)
Lauren C. Ravkind (*pro hac vice* forthcoming)
Anna T. Neill (*pro hac vice* forthcoming)
SPERLING KENNY NACHWALTER LLC
Four Seasons Tower, Suite 1100
1441 Brickell Avenue
Miami, FL 33131
Telephone: (305) 373-1000
Email: sep@sperlingkenny.com
Email: lcr@sperlingkenny.com
Email: atn@sperlingkenny.com

Attorneys for Plaintiffs

Exhibit A

States that Prohibit Automatic Substitution Unless Patient Pays Less		
State	**Statute**	**Percentage of Total U.S. Population**
California	Cal.Bus. & Prof. Code § 4073(a-c), (e)	11.9%
Texas	Tex. Occ. Code § 562.008(b); Tex. Occ. Code § 562.009(a); Tex. Occ. Code § 562.011(a-b)	8.8%
Illinois	225 ILCS 85/25	3.9%
North Carolina	N.C. Gen. Stat. § 90-85.28(a), (c)	3.1%
Michigan	M.C.L.A. 333.17755(1), (4)	3.0%
Virginia	Va. Code § 54.1-3408.03(A), (D)	2.6%
Maryland	Md. Code, Health Occ. § 12-504(d)(1-2)	1.9%
Missouri	Mo. Ann. Stat. § 338.056	1.9%
Colorado	C.R.S.A. § 12-280-125(1), (3-4)	1.8%
Alabama	Ala. Code § 34-23-8(a)	1.5%
Louisiana	La. R.S. 37:1164; La. R.S. 37:1226.1; La. Admin. Code tit. 46, § LIII-2517(B)(3)	1.4%
Oregon	Or. Rev. Stat. § 689.515(2), (4-5)	1.2%
Connecticut	Conn. Gen. Stat. § 20-619 (b), (h)	1.1%
Arkansas	AR Code § 17-92-503 (a-b)	0.9%
Kansas	K.S.A 65-1626; K.S.A. 65-1637(g)	0.9%
Mississippi	Miss. Code § 73-21-117	0.9%
New Mexico	N.M. Stat. § 26-3-3(A)	0.6%
Idaho	IDAPA 24.36.01.404	0.5%
New Hampshire	N.H. Rev. Stat. Ann. § 318:47-d; N.H. Rev. Stat. Ann. § 146-B:2	0.4%
Montana	Mont. Code § 37-7-505(1); Mont. Code § 37-7-506(1)	0.3%
D.C.	DC Official Code §48-803.02(a); DC Official Code §48-803.03(a)	0.2%